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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,069	09/05/2003	David A. Hanson	6683.43USC1	8340

43541 7590 11/22/2005

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EXAMINER

SHAFFER, RICHARD R

ART UNIT PAPER NUMBER

3733

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/656,069

Applicant(s)

HANSON ET AL.

Examiner

Richard R. Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-46 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date 9/5/03.

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Priority

This application is a continuation of application 09/896,926 filed on 6/28/2001, which is a continuation-in-part of 09/611,237 filed on 7/6/2000. The examiner has found the claims in this application to be directed to the additional material presented solely in the 09/896,926. Thus all claims have been examined in reference to a filing date of 6/28/2001.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 36-46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for rasp having a handle accepted by a hollow shaft of a chisel, does not reasonably provide enablement for a chisel that simply slides over the handle of a rasp in such a way as to not require the chisel to encompass the handle of the rasp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to construct the invention commensurate in scope with these claims. Claims 37-46 have been rejected as being dependent upon claim 36.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3733

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winslow et al (US Patent 6,083,225) in view of Hamada (US Patent 6,436,101).

Winslow et al disclose a "surgical retractor" (10), which could be used as a chisel due to its blades (20). It has a hollow inner cavity to which slot (16) interfaces. Column 3, lines 25-28 discuss how the cavity is intended to guide surgical instrumentation to the surgical site. Column 5, lines 53-58 discuss how the slots (16) can also permit lateral introduction of spinal instrumentation. This final point would require instrumentation to include a radial protrusion in order to be handled by the surgeon. Winslow et al further disclose a two-piece implant (s and 200) where s is a bone growth material and 200 is a support member.

Winslow et al fails to explicitly disclose the use of a rasp with the device (10), however it is well known in the art to utilize a rasp, rongeur, osteotome, and the like when preparing bone surfaces for implantation. Hamada discloses a rasp for use in spinal surgery (501) with a detachable head portion (503) connected by a pin (131) that limits the rotation of the head portion with respect to the handle (105). While the dimensions of the rasp are unknown in relation to the chisel of Winslow et al, it is normally within the skill of one of ordinary skill in the art to simply scale up or down a device as long as the means to do so existed at the time of invention. The motivation to allow sliding of Hamada's rasp within the guide of Winslow, et al includes limiting the

Art Unit: 3733

area obscured to the surgeon during a procedure as well as controlling/guiding an instrument safely into the body, especially one as critical as the spine.

Hamada's rasp (503) as shown in **Figures 43 and 44** has rasping structures on the top (507) and bottom (521) surfaces. One of ordinary skill in the art would have also readily seen the need to interface with the rasp head to slide it back and forth while within the cavity (16) of Winslow et al. Thus, pin (131) or a handle structure that would insert through the slot (16) of Winslow et al to connect to the bore (517) of Hamada would have been a simple substitution of function. With the handle in place (e.g. 131), it would also limit rotation of the rasp head within the hollow cavity of chisel (10). At this orientation, the top blade of the chisel would pass over the top surface of the rasp and the bottom blade would pass below the bottom surface of the rasp.

It is inherent that the bone implant (s and 200) be shaped to fit within the regions prepared by the rasp and chisel, else there is no point in preparing the site for implantation.

In regard to claims 44 and 45, applicant failed to disclose any criticality in using a c-shaped rasp head and c-shaped implant support. Examiner after reading the specification and analyzing the drawings has determined that the c-shape is solely a design choice. Applicant is using a c-shaped rasp that creates a circular removal of bone tissue with the support portion of the implant being inserted by the "c" opening. The bone graft material is then pushed in through the same opening. Hamada is using a circular rasp to also create a circular removal of bone tissue and implanting a subsequent circular support implant (**Figure 62**). The implant of Hamada has a bore

